

errors have been corrected, and the drawings will be attended to upon receipt of a Notice of Allowance.

Further, the application incorporated by reference WO 90/04411 which corresponds to U.S. Patent No. 5,523,089 issued from USSN 08/079,601. The application now claims a lineage to USSNs 08/079,601, 07/924,798, and 07/422,881 and Danish application 5902/88, filed October 24, 1988, such that the present application has an effective filing date of October 24, 1988. A new Declaration For Patent Application will be filed in due course.

In this regard, with reference to U.S. Patent No. 5,523,089, it is noted that at column 16 there is the disclosure of immunization with OspA to evoke a humoral and/or secretory, and or cell-mediated immunity and that as noted in the Office Action (at page 6) column 18 of U.S. Patent No. 5,523,089 discloses OspA vaccines for oral administration, nasal administration or rectal administration, providing a teaching of mucosally and orally administering OspA. The teachings of administration of OspA orally, nasally or rectally is mucosal administration. And, it is known that mucosal administration enables a local immune response, such that the teachings of various immunity at column 16 are also teachings of mucosal and oral administration of OspA. Thus, the present claims are fully taught, enabled and supported in the Danish priority document; and, the present claims are entitled to an October 24, 1988

filing date. To assist the Examiner in likewise reaching that conclusion, the claims are amended to employ terms as in the issued claims of U.S. Patent No. 5,688,512, e.g., "substantially pure". No new matter is added.

Claims 11 and 12 were rejected under Sections 101 and 102(e) on the basis of U.S. Patent No. 5,688,512 (Office Action at 2-3)

Claim 11 is cancelled, without prejudice, admission, or any intention of creating any estoppel as to equivalents, or any surrender of subject matter; and, claim 12 depends on claim 1. These amendments obviate the Section 101 and 102(e) rejections.

Furthermore, submitted herewith is the Declaration of Drs. Barbour and Luke showing that the inventive entities of U.S. Patents Nos. 5,688,512 and 5,523,089 are not "another" as to the present inventive entity, also obviating the Section 102(e) rejection.¹

Reconsideration and withdrawal of the Section 101 double patenting and Section 102(e) rejection are respectfully requested.

The claims were rejected under Section 103 and under the judicially created doctrine of obviousness-type double patenting in view of USSN 08/375,993 (Office Action at 3-4).

¹ The Declaration is executed by inventor Luke; a Declaration by inventor Barbour will follow in due course.

The Declaration of Drs. Barbour and Luke showing that the inventive entities of U.S. Patents Nos. 5,688,512 and 5,523,089 are not "another" as to the present inventive entity, also obviates the Section 103 rejection based on USSN 08/375,993, now U.S. Patent No. 5,688,512.

With respect to the obviousness-type double patenting rejection, it is respectfully submitted that the Examiner has failed to make a *prima facie* case of double patenting.

Double patenting of the "obviousness-type" exists when the subject matter of the claim in issue would have been obvious from that of the claim of a prior commonly assigned patent **and vice versa**. Carman Industries, Inc. v. Wahl et al., 220 USPQ 481 (Fed. Cir. 1983). This reasoning was confirmed by the Court of Appeals for the Federal Circuit in In re Braat, 19 USPQ2d 1289 (Fed. Cir. 1991), wherein the Court stated:

We hesitate to characterize the Dil [cited patent] invention as an "improvement" over the Braat [rejected application] invention. The word "improvement" implies that it was developed specifically for use with the "basic" invention, and thus must have come later in time. . . .

However, we agree that the reasoning of *Borah* and *Chisum*, §9.03[2][c] is applicable in the present case. . . . A double patenting rejection is sustainable here only if claims 5/1 and 6/1 of Dil are not patentably distinct from the subject matter defined by the rejected claims of Braat, and the Board erred in sustaining the double patenting

rejection without making such a "two-way" determination.

. . . .

It is true that allowance of the Braat application will result in some timewise extension of [assignee] Philips' patent protection of the Dil structure. This is because Braat's claims dominate the invention of Dil claims 5/1 and 6/1. As our predecessor court pointed out in *Borah*, in analogizing the *Stanley* decision, "We see . . . that as a matter of law the extension of protection objection is not necessarily controlling." . . .

. . . There are situations where the extension is justified. See *Borah*; *In re Kaplan*, 798 F.2d 1574, 1577-78, 229 USPQ 678, 681-82 (Fed. Cir. 1986). This case presents such a situation. 19 USPQ2d at 1292 and 1293.

It is respectfully submitted that the Office Action fails to meet the criteria for an obviousness rejection, and misapprehends the law of double patenting.

As recently stated by the Federal Circuit:

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious **unless the prior art suggests the desirability of the modification.**

In re Fritch, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) (emphasis added). See also In re Kaplan, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986) ("**there must be some clear evidence to establish why the variation [between claims of a patent and of the application] would have been obvious [for double patenting**

rejection] which can properly qualify as 'prior art' ... if obviousness predicated on the level of skill in the art, prior art evidence is needed to show what that level of skill was"). See also In re Kaplan, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986) (only claims of patent or patent application, not its disclosure, available for use in double patenting rejection).

Any dominance of the presently claimed subject matter by the claims of U.S. Patent No. 5,688,512 is not controlling in determining double patenting. See In re Kaplan, 229 U.S.P.Q. 678, 681 (Fed. Cir. 1986) ("This commonplace situation [of one patent dominating another] is not, per se double patenting as the board seemed to think").

The Office Action has not demonstrated that the required two-way obviousness exists, and fails to cite any evidence for why claims of U.S. Patent No. 5,688,512 are obvious in view of the present claims and vice versa.

Indeed, the double patenting rejection in the Office Action is deficient in a number of ways, including:

First, the double patenting rejection fails to identify particularly which claim or claims of U.S. Patent No. 5,688,512 allegedly render the present claims obvious.

Secondly, the Office Action fails to show how the particular species in the present claims - mucosally administering and orally administering - would be obvious from the claims of U.S. Patent No. 5,688,512.

Thirdly, the Office Action fails to show how the particular species in the present claims - mucosally administering and orally administering - renders obvious the claims of U.S. Patent No. 5,688,512.

And, fourthly, the Office Action fails to show how the present claims are not a patentably distinct species within the genus of the claims of U.S. Patent No. 5,688,512.

With respect to each of these points, it is noted that only the claims of the present application and of U.S. Patent No. 5,688,512 are available to the Examiner, and not the disclosure of the present application or the specification of U.S. Patent No. 5,688,512.

A species (or subgenus) may be patentably distinct from a genus such that a first patent issues to one party with claims directed to the genus, and a second patent issued to another party with claims directed to the species or subgenus. See e.g., In re Baird, 29 USPQ 2d 1550 (Fed. Cir. 1994); In re Jones, 21 USPQ 2d 1941 (Fed. Cir. 1992); In re Taub, Wendler, and Slates, 146 USPQ 384 (C.C.P.A. 1965); In re Petering, 133 USPQ 275 (C.C.P.A. 1962); Hsing v. Myers, 2 USPQ2d 1861 (BOPAI 1987).

The Commentary to Rules of Practice, 49 Fed. Reg. 48416, 48433 (Dec. 12, 1984), 1050 O.G. 395 (Jan. 29, 1985), corrected to 50 Fed. Reg. 23122 (May 31, 1985), 1059 O.G. 27 (Oct. 22, 1985), provides in pertinent part:

Thus, if a species is patentable over a genus, the species is a "separate patentable invention" from the genus. Compare In re Taub, 348 F.2d 556, 146 USPQ 384 (C.C.P.A., 1965).

In this regard, the Examiner's attention is also directed to In re Sasse, 207 U.S.P.Q. 107 (C.C.P.A. 1980), wherein the Court of Customs and Patent Appeals held that a claim to a genus and a claim to a species within the genus are not claims to the same or substantially the same subject matter in the sense of 35 U.S.C. §135(b).

Thus, the Office Action has not made any case of double patenting.

Furthermore, the basis for the double patenting rejection, "to prevent ... timewise extension of the 'right to exclude'" is not applicable in the present situation, since by the amendments herewith, the patent issuing from this post-GATT application will have a term of twenty years from October 18, 1989, i.e., a term up to October 18, 2009, whereas U.S. Patent No. 5,688,512 will expire in 2014 (17 years from the November 18, 1997 issue date).

Accordingly, there is no basis in fact or law for the double patenting rejection.

Reconsideration and withdrawal of the Section 103 and double patenting rejections based on U.S. Patent No. 5,688,512 are respectfully requested.

Claims 1 to 12 were rejected under Section 112 at pages 4 to 5 of the Office Action.

The terms forming the bases for the Section 112, second paragraph rejection are either no longer in the claims or are amended in accordance with the Examiner's suggestion, such that the Section 112 rejection is obviated; and, it is respectfully requested that it be reconsidered and withdrawn.

Claims 1 to 4 and 6 to 12 were rejected under Section 102(e) as anticipated by U.S. Patent No. 5,523,089.

By the amendments and Declaration herewith, the 089 patent is not prior to the present application; and, the inventive entity thereof is not "another" as to the present inventive entity. Reconsideration and withdrawal of the Section 102(e) rejection are respectfully requested.

Claims 5 was rejected under Section 103 as unpatentable over U.S. Patent No. 5,523,089 in view of Flavell and claims 1 to 12 were rejected as anticipated under Section 102(b) on the basis of Flavell.

By the amendments, Flavell is not prior to the present application; and, as discussed above, nor is U.S. Patent No. 5,523,089. Further, as discussed above, the inventive entity of the 089 patent is not "another" as to the present inventive entity. Reconsideration and withdrawal of the Sections 102(b) and 103 rejections are respectfully requested.

In regard to these rejections the Examiner is respectfully reminded that in cases where an application names a different inventive entity than an issued patent and the application and patent arise from the same earlier application, the Federal Circuit has held that the patent is not Section 102(e) art. Thus, in the present situation, the 089 patent is not prior art. In particular, in In re Kaplan, 229 U.S.P.Q. 678 (Fed. Cir. 1986), the Court held that it was improper to cite the disclosure of Kaplan, U.S. Patent No. 3,944,588 against the descendent Kaplan and Walker joint application.

Similarly, in Applied Materials v. Gemini Research Corp., 5 U.S.P.Q.2d 1127, 1129-30 (Fed. Cir. 1988), U.S. Patent Nos. 3,623,712, 4,047,496 and 4,081,313 all arose from the same application, but due to each claiming different subject matter each named a different inventive entity (although there were common inventors). The district court had held that the '712 patent (naming McNeilly and Benzing as inventors) was prior art against the '313 patent (naming McNeilly, Benzing, and Locke as inventors), i.e., that the invention of the '712 patent was invented by a different inventive entity, and that the '313 patent was valid as anticipated under §102(e) by the '712 patent.

In reversing the District Court's holding, the Federal Circuit noted that the fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art and recognized that "even though ...

conceived by different inventive entities ... if they share one or more persons as joint inventors, the 35 U.S.C. §102(e) exclusion for ... 'another' is not satisfied" (emphasis added).

According to Kaplan and Applied Materials, the inventive entity of the 089 patent is not "another" as to the present inventive entity and therefore, those applications cannot be employed as art under Section 102(e). Furthermore, Applicants have gladly herewith provide a Declaration that they are not another as to the inventive entity of the 089 patent and U.S. Patent No. 5,688,512.

Claims 11 and 12 were rejected under Section 102(b) as anticipated by Simon, Wilske, Benach, or Fuchs.

Simon and Fuchs are not prior art as to the present application, by the amendments herewith; and as determined during the prosecution of U.S. Patent No. 5,688,512, neither Wilske nor Benach teach or suggest substantially pure OspA, or any vaccine containing such, *inter alia*. Also, none of these documents teach or suggest oral or mucosal administration. Furthermore, claim 11 is cancelled and claim 12 now depends on claim 1, rendering moot this rejection.

Accordingly, reconsideration and withdrawal of the Section 102(b) rejection based on Simon, Wilske, Benach and Fuchs are respectfully requested.

Moreover, in view of the amendments, remarks and enclosures herewith, the present application is in condition for

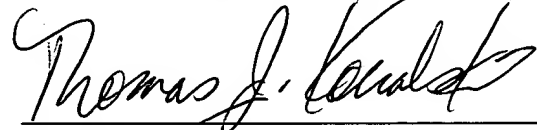
allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

INDEED, IF THE NEXT PAPER TO ISSUE IS NOT A NOTICE OF ALLOWANCE, APPLICANTS RESPECTFULLY REQUEST AN INTERVIEW AND SUPERVISORY REVIEW BY THE GROUP DIRECTOR AND MR. RICHARD SCHWARTZ, i.e., AN INTERVIEW WITH THOSE INDIVIDUALS AND THE EXAMINER; AND TO ANY EXTENT NECESSARY, THIS PAPER IS A PETITION FOR SUCH SUPERVISORY REVIEW AND INTERVIEW, WITH THE COMMISSIONER AUTHORIZED TO CHARGE ANY REQUISITE FEE THEREFOR TO DEPOSIT ACCOUNT NO. 50-0320.

Respectfully submitted,

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